K 130070

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924-8566 Japan

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
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510(k) Summary (in accordance with 21 CFR 807.92)

1. Company

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Ishikawa 924-8566 Japan
Tel: +81 (76) 274-2468
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2. Contact Person

Hiroaki Hashimoto

3. Date of Summary

December 25th, 2012

4. Device Information

- Trade Name/Model: RadiForce RX440
- Common Name: 4MP Color LCD Monitor
- Classification Name: System, Image Processing, Radiological
- Regulation Number: 21 CFR 892.2050, Product Code LLZ

5. Predicate Device

- 4MP Color LCD Monitor, RadiForce RX430 (K112466)

6. Device Description

The RadiForce RX440 is a color LCD monitor for viewing medical images other than those of mammography. The matrix size (or resolution) of the panel is 2,560 x 1,600 pixels (4MP) with a pixel pitch of 0.2505 mm.

Since factory calibrated display modes, each of which is characterized by a specific tone curve (including DICOM GSDF), a specific luminance range and a specific color temperature, are stored in lookup tables within the monitor, the tone curve is e.g. DICOM compliant regardless of the display controller used.

Model variations with cosmetic differences are distinguished by characters attached to the name of the base model "RX440" such as "RX440-AR", a model with an Anti-Reflective coating on the screen surface although the hardware design, components and labeling remain unchanged.

RadiCS is application software to be installed in each workstation offering worry-free quality control of the diagnostic monitors including the RadiForce RX440 based on the QC standards and guidelines and is capable of quantitative tests and visual tests defined by them. The RadiCS is included in this 510(k) submission as an accessory to the RadiForce RX440.

7. Intended Use

This product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

8. Comparison of Technological Characteristics

The comparison table below enumerates information derived from the product literature of the each device and different technological characteristics are discussed in it:

Attributes	Eizo RadiForce RX440	Eizo RadiForce RX430	Explanation of Differences
Display Performance/Specifications			
Screen technology	TFT Color LCD Panel (IPS)	TFT Color LCD Panel (IPS)	-
Viewing angle (H, V)	H: 176°, V: 176° @CR=10	H: 170°, V: 170° @CR=50	Eizo uses typical data for very low contrast provided by the panel manufacturers
Active screen size	641.28 mm x 400.8 mm	641.28 mm x 400.8 mm	-
Resolution	4MP (2,560 x 1,600)	4MP (2,560 x 1,600)	
Aspect ratio	16:10	16:10	-
Pixel pitch	0.2505 mm x 0.2505 mm	0.2505 mm x 0.2505 mm	-
Maximum luminance	750 cd/m^2	1,000 cd/m^2	Though smaller maximum luminance

DICOM calibrated luminance	400 cd/m^2	400 cd/m^2	value usually means shorter warranty period of the calibrated luminance, the warranty period of the proposed device is longer than that of the predicate device due to the LED backlight deteriorating more slowly than the CCFL backlight.
Contrast ratio	1100:1	1100:1	Eizo uses typical contrast ratio data provided by panel manufacturers.
Backlighting	LED	CCFL	See main text below.
Display Colors	10-bit colors 1.07 Billion (maximum) colors 8-bit colors: 16.77 million from a palette of 68 billion colors	10-bit colors 1.07 Billion (maximum) colors 8-bit colors: 16.77 million from a palette of 68 billion colors	-
Luminance non-uniformity compensation	Digital Uniformity Equalizer	Digital Uniformity Equalizer	-
Video Signal Input			
Input video signals	DVI-D (dual link) x 1, DVI-D (single link) x 1, DisplayPort x 1	DVI-D (dual link) x 1 , DisplayPort x 1	-
Scanning Frequency (H, V)	31 - 159 kHz, 29 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz, 29.5 - 30.5 Hz	31 - 100 kHz, 29.5 - 61 Hz (VGA Text: 69 - 71 Hz) Frame synchronous mode: 59 - 61 Hz, 29.5 - 30.5 Hz	Wider frequency ranges are supported by the proposed device.
Dot Clock	280 MHz	290 MHz	-
Power Related Specifications			
Power Requirements	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	AC 100 - 120 V, 200 - 240 V: 50 / 60 Hz	-
Power Consumption / Save Mode	167 W / Less than 0.7 W	200 W / Less than 1 W	The proposed device consumes less power than the predicate device.
Power Management	DVI DMPM, DisplayPort 1.1a	DVI DMPM, DisplayPort 1.1a	-
Miscellaneous Features/Specifications			
QC software	RadiCS	RadiCS	-

Sensors	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	Backlight Sensor, Integrated Front Sensor, Presence Sensor, Ambient Light Sensor	-.
USB Ports / Standard	1 upstream, 2 downstream / Rev. 2.0	1 upstream, 2 downstream / Rev. 2.0	-
Dimensions w/o stand (W x H x D)	720 x 498 x 119 mm	720 x 498 x 119 mm	-

For the substantial equivalence determination, only the difference of the backlights needs further evidences by performance testing.

9. Performance Testing

The following bench tests were performed on the RadiForce RX440:

- Verification of the conformance to DICOM GSDF as specified in *Assessment of Display Performance for Medical Imaging Systems* by AAPM Task Group 18 (TG18 guideline)
- Measurement of the luminance non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity non-uniformity characteristics of the display screen as specified in the TG18 guideline
- Measurement of the chromaticity at the center of the display screen at 5%, 50% and 95% of the maximum luminance as specified in *Guidance for Industry and FDA Staff: Display Accessories for Full-Field Digital Mammography Systems-Premarket Notification (510(k)) Submissions*
- Visual check of presence or absence of miscellaneous artifacts on the display screen as specified in the TG18 guideline
- The maximum number allowed for each type of pixel defects/faults agreed with the manufacturer from which Eizo buys the LCD panels for RadiForce RX440

None of the tests revealed behaviors inconsistent with the expected performance.

No animal or clinical testing was performed on the RadiForce RX440.

10. Conclusion

The 4MP Color LCD Monitor, RadiForce RX440 is substantially equivalent to the predicate device with respect to technical characteristics, performance, application and intended use. The specifications of the primary component employed by the proposed device are the same as those of the predicate device and other differences have been independently validated. Any differences between the devices do not affect safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-002

February 8, 2013

Eizo Nanao Corporation
c/o Hiroaki Hashimoto, Manager
Medical Systems Standards
153 Shimokashiwano
Hakusan
JAPAN 924-8566

Re: K130070
Trade/Device Name: RadiForce RX440
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: Class II
Product Code: LLZ
Dated: January 9, 2013
Received: January 18, 2013

Dear Hiroaki Hashimoto:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set

forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Parts 801 and 809), please contact the Office of *In Vitro* Diagnostics and Radiological Health at (301) 796-5450. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Sean M. Boyd -S for

Janine M. Morris
Director, Division of Radiological Health
Office of *In Vitro* Diagnostics and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use Form

510(k) Number (if known): _____

Device Name: 4MP Color LCD Monitor, RadiForce RX440

Indications for Use:

This product is intended to be used in displaying and viewing digital images for review and analysis by trained medical practitioners. It does not support the display of mammography images for diagnosis.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of *In Vitro* Diagnostics and Radiological Health (OIR)

Sean M. Boyd -S

(Division Sign Off)
Division of Radiological Health
Office of *In Vitro* Diagnostic and Radiological Health
510(k) K130070